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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.				
10/617,326	07/10/2003	Bastiaan Driehuys	PM0026 DIV	2824				
7590 Amersham Health, Inc. 101 Carnegie Center Princeton, NJ 08540		12/28/2007	<table border="1"><tr><td colspan="2">EXAMINER</td></tr><tr><td colspan="2">JONES, DAMERON LEVEST</td></tr></table>		EXAMINER		JONES, DAMERON LEVEST	
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/617,326	<b>Applicant(s)</b> DRIEHUYS ET AL.	
	<b>Examiner</b> D. L. Jones	<b>Art Unit</b> 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 10/30/07 & 11/20/07.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 64-69 and 80 is/are pending in the application.
- 4a) Of the above claim(s) 80 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 64-69 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **ACKNOWLEDGMENTS**

1. The Examiner acknowledges receipt of the acceptable terminal disclaimers filed 11/20/07. In addition, the Examiner acknowledges receipt of the amendment filed 10/30/07 wherein claims 1-63, 70-79, and 81-88 were canceled.

**Note:** Claims 64-69 and 80 are pending.

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/30/07 has been entered.

## **RESPONSE TO APPLICANT'S ARGUMENTS/AMENDMENT**

3. The Applicant's arguments and/or amendment filed 10/30/07 to the rejection of the claims made by the Examiner under double patenting have been fully considered and deemed withdrawn-in-part for the reasons set forth below.

### **Double Patenting Rejections**

I. The double patenting rejection over US Patent No. 6,630,126 is WITHDRAWN because Applicant has filed an acceptable terminal disclaimer.

II. The double patenting rejection over US Patent No. 6,808,699 is WITHDRAWN because Applicant has filed an acceptable terminal disclaimer.

III. The provisional rejection of claims 64-69 on the ground of non-statutory obviousness-type double patenting as being unpatentable over claims 26 and 30 of copending application number 10/356,240 is MAINTAINED for reasons of record in the office action mailed 6/19/07 and those set forth below.

IV. The provisional rejection of claims 64-69 on the ground of non-statutory obviousness-type double patenting as being unpatentable over claims 49 and 53 of copending application number 10/761,794 is MAINTAINED for reasons of record in the office action mailed 6/19/07 and those set forth below.

According to MPEP 804, if a "provisional" nonstatutory obviousness-type double patenting (ODP) rejection is the only rejection remaining in the earlier filed of the two pending applications, while the later-filed application is rejectable on other grounds, the examiner should withdraw that rejection and permit the earlier-filed application to issue as a patent without a terminal disclaimer. If the ODP rejection is the only rejection remaining in the later-filed application, while the earlier-filed application is rejectable on other grounds, a terminal disclaimer must be required in the later-filed application before the rejection can be withdrawn.

If "provisional" ODP rejections in two applications are the only rejections remaining in those applications, the examiner should withdraw the ODP rejection in the earlier filed application thereby permitting that application to issue without need of a terminal disclaimer. A terminal disclaimer must be required in the later-filed application before the ODP rejection can be withdrawn and the application permitted to issue. If both applications are filed on the same day, the examiner should determine which

application claims the base invention and which application claims the improvement (added limitations). The ODP rejection in the base application can be withdrawn without a terminal disclaimer, while the ODP rejection in the improvement application cannot be withdrawn without a terminal disclaimer.

Thus, since 10/356,240 was filed prior to the instant application, a terminal disclaimer is necessary in order to overcome the double patenting rejection. However, for 11/623,352 since the filing date is later than that of the instant invention when only the provisional rejection is present, then the ODP over 11/623,352 will be withdrawn.

#### **WITHDRAWN CLAIMS**

4. Claim 80 is withdrawn from further consideration by the Examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention/species.

#### **NEW GROUNDS OF REJECTIONS**

##### **Double Patenting Rejection**

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29

USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 64-69 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 4-6, 7, 15, and 16 of U.S. Patent No. 6,491,895. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to evaluating the effects of drug therapy associated with a cardiac/pulmonary condition wherein a pharmaceutical is administered to a subject. The claims differ in that the patented claims specifically state that multiple MR spectroscopic response data is obtained while in the instant invention, it is not specifically stated that multiple spectroscopic MR data is obtained. However, a skilled artisan would recognize that the instant invention allows

for multiple spectroscopic MR data and in claim 65 of the instant invention, it is specifically stated that at least two sets of data are obtained during the evaluation of the drug therapy procedure. Hence, both the patented and instant invention discloses overlapping subject matter.

7. Claims 64-69 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5 and 9 of U.S. Patent No. 7,179,450. Although the conflicting claims are not identical, they are not patentably distinct from each other because while the patented invention is directed to a method of evaluating physiological response to a therapeutic agent and the instant invention is directed to a method of evaluating drug therapy, both sets of claims are disclose overlapping subject matter. Specifically, the physiological response in the patented invention may be that of how a subject responds to the therapeutic agent (drug) administered. Hence, the skilled practitioner would recognize that the phrase 'physiological response' encompasses 'drug therapy' response after the administering of a pharmaceutical agent.

#### **COMMENTS/NOTES**


8. It is once again noted that Applicant elected Group VII without traverse in the reply filed 8/14/06. Group VII is drawn to a method of evaluating the efficacy of a targeted drug therapy wherein the treatment condition is cardiac/pulmonary and a pharmaceutical preparation is administered. The search has not been extended beyond

the elected invention. Thus, Applicant is respectfully requested to amend the claims to read on the elected invention only.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
D. L. Jones  
Primary Examiner  
Art Unit 1618

December 21, 2007